K080654

# 510(k) Premarket Notification Submission:

MAY - 8 2008

## Summary of Safety and Effectiveness for PAJUNK®'s Kit for balloon aided laparoscopy

**Date of Preparation: April 12th 2008**


**Submitter Information/ production site:**

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**Contract Sterilizer:**

STERIGENICS GERMANY GMBH
Rheingaustrasse 190-196
65203 Wiesbaden, GERMANY
**Registration Number:** 3002807090
**Operations:** Contract Sterilizer
**Status:** Active


**Device Information:**

| | |
|---|---|
| Device Name: | **PAJUNK®'s Kit for balloon aided laparoscopy** |
| Trade Names: | **Balloon Laparoscopes** |
| Common Name: | **Kit, balloon, trocar, port** |
| Classification Name: | **Endoscope and accessories** |
| Classification Reference: | **21 CFR §876.1500, April 1, 2007** |
| Establishment Registration Number: | **9611612** |
| Regulatory Class: | **II** |
| Product Code: | **GCJ** |
| Panel: | **Gastroenterology/Urology** |
| Predicate Devices: | 1. **K012771 Trocar Sleeve and accessories – PAJUNK®**<br>2. **K063528 TrokaSys – PAJUNK®** |

## Device Description:

The kit provides a common port with trocar and valve closure (for gaining acces for minimal invasive surgery) packed in a separate bag within the sterilized unit and a rigid balloon guidance with obturator and filling syringe (for insertion of the endoscopic visualisation device) packed in another separate bag. Both units are available seperately and as a procedure unit.

It is especially intended for diagnostics and aftercare in minimal invasive procedures.

Due to the length of the balloon guidance and the clinical practice there is no need to create a pneumoperitoneum via insufflation

The port may be left in place for up to 10 days with the seal closure trocar in place.

The kit is sterile and intended for single use.

## Indications for use:

**PAJUNK®'s Kit for balloon aided laparoscopy** is intended for making incisions into the patients body to allow insertion of endoscopes and endoscopic accessories during general and minimal invasive surgical procedures.

## Additional Claims

It is especially intended for diagnostics and aftercare.

Due to the length of the balloon guidance and the clinical practice there is no need to create a pneumoperitoneum via insufflation.

The port may be left in place for up to 30 days.

## Predicate Devices:

**PAJUNK®'s Kit for balloon aided laparoscopy**, the subject device of this submission, combines technical features of PAJUNK®'s devices already approved for market. Predicate devices with identical or at least similar indications of use are:

1. K012771 Trocar Sleeve and accessories (balloon systems), PAJUNK®
2. K063528 TrokaSys, PAJUNK®

While the predicate devices are indicated for minimal invasive procedures the subject device is indicated for inserting and guiding optical endoscopes for aftercare and diagnostics. The detailed discussion of substantial eqivalence can be found in Section 12 of this submission.

## Sterilization

The sterilization process is the same as that used for all PAJUNK® Products already cleared for market. It has been validated for double-bag packages with the balloon systems and the disposable trocars TrokaSys, predicate devices of this submission.

**Technology Characteristics:**

The Kit consists of the following components arranged in two bags for two steps in procedure:

| | |
|---|---|
| Bag 01 | Port |
| | Trocar |
| | Seal closure trocar |
| Bag 02 | Balloon guidance |
| | Obturator |
| | Filling syringe (30ml) |

**Conclusion:**

The comparison between the predicate devices and the proposed devices in section 12 of this submission as well as the validated sterilization process and biocompatibility data demonstrates that the proposed Kit is substantially equivalent to the predicate devices and safe and effective. The optional use of optical devices (image giving endoscopes) in order to monitor the procedure and to conduct manually operated interventions under sight/ view are at least as safe and effective as common techniques are, actually this is intended to enhance safety and effectiveness..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2008

Pajunk GmbH Medizintechnologie
% Christian Quass
Director, Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen, Germany

Re: K080654
Trade/Device Name: PAJUNK®'s Kit for balloon aided laparoscopy
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 21, 2008
Received: April 23, 2008

Dear Christian Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for use

510(k) Number: K080654

Device Name: PAJUNK®'s Kit for balloon aided laparoscopy

Indications for Use:

**PAJUNK®'s Kit for balloon aided laparoscopy** is intended for making incisions into the patients body to allow insertion of endoscopes and endoscopic accessories during general and minimal invasive surgical procedures.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for MRN

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K080654